

REMARKS

Claims 1-24 are pending. Applicants thank the Examiner for continuing to allow claims 13-24, and for indicating that claims 9-12 would be allowable if rewritten in independent form to include all of the subject matter of the base claim and any intervening claims. Claims 1-8 stand rejected.

Applicants amend claim 1 to clarify that the expandable balloon is adapted to be *positioned at a treatment site*, and that the pressure-relief valve is configured to open and release *irrigation fluid to the treatment site* in response to excess pressure exerted on the expandable balloon. Support for this amendment can be found throughout the specification and in the drawings, for example, at page 2, lines 16 to 26. No new matter is added.

Applicants also amend claims 9 and 11 into independent format to include all of the limitations of claim 1 as originally filed. The Examiner indicated in a first Office Action that claims 9-12 would be allowable if rewritten in independent format to include all of the subject matter of the base claim and any intervening claims. Accordingly, amended claim 9 (as well as depend claim 10) and amended claim 11 (along with dependent claim 12) are now believe to be in condition for allowance and allowance thereof is respectfully requested.

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Rejection Pursuant to 35 U.S.C. §102

Claims 1-8 stand rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,800,493 of Stevens et al. (Stevens). The Office Action asserts that Stevens discloses an anchoring balloon device having a flexible elongate member (3) with an interior lumen extending therethrough for the delivery of an inflation fluid, an expandable balloon (5) disposed about a portion of the elongate member and in fluid communication with the lumen via at least one port, and a pressure-relief valve (18) for regulating the pressure of fluid within

the expandable balloon.

Amended claim 1 recites a pressure-relief valve that is configured to open and release *irrigation fluid to the treatment site* in response to excess pressure exerted on the expandable balloon. Stevens does not teach or even suggest such a valve. Rather, Stevens discloses a device having a distensible bladder that can only be inflated and deflated by an external valve.

Manipulation of the fluid fill valve 18 enables the operator of the system to control the amount of fluid 25 in the fluid system, inflation and deflation of the distensible bladder by adding or removing fluid, respectively, and pressure of the fluid 25 in the system.

(Col. 4, lines 60-64.) As set forth at Col. 5, lines 34-40 and lines 50-56, and Col. 6, lines 1-10, the pressure within the system is controlled by manually pressing and depressing a plunger that is associated with the fluid fill valve (18) to inflate and deflate the pressure within the expandable bladder. Stevens does not teach or even suggest a valve that can release *irrigation fluid to the treatment site* in response to the application of pressure on the expandable balloon.

In fact, Stevens requires a sealed system such that “[e]ach of the parts of the fluid path is in fluid communication providing constant fluid pressure within the entire fluid system and allowing measurement of pressure of the end attached to the control unit 30.” (Col. 5, lines 10-15.) The distensible bladder, therefore, cannot release *irrigation fluid at the treatment site* as such a configuration would not allow the pressure to be measured by the control unit.

Accordingly, claim 1 is not anticipated by Stevens, and thus represents allowable subject matter. Claims 2-8 are allowable at least because they depend from an allowable base claim.

Rejection Pursuant to 35 U.S.C. §103

Claims 1-8 are also rejected pursuant to 35 U.S.C. §103 as being obvious over Stevens in view of U.S. Patent No. 5,429,483 of Tamari. The Office Action states that Tamari disclose

a pressure relief valve for an extracorporeal circuit to control pressure, and thus it would have been obvious to one having ordinary skill in the art to modify Stevens to include one of the pressure relief valves disclosed by Tamari “since the use thereof would provide an anchoring balloon device with an alternative pressure relief vale.” Applicants disagree.

As previously stated above, Stevens does not teach or even suggest an anchoring balloon device having a pressure-relief valve that is configured to open and release *irrigation fluid to the treatment site* in response to excess pressure exerted on the balloon. Tamari does not remedy the deficiencies of Stevens. Tamari is directed to a pumping system that is used for extracorporeal circulation to pump blood through a patient’s body during, for example, a bypass procedure. The device does not include any type of inflatable balloon structure, much less one in which pressure exerted on the balloon is effective to release *irrigation fluid to the treatment site* at which the balloon is positioned. In fact, the Tamari device only circulates fluid within a closed system. Thus, merely replacing the valve on the Stevens device with one of the valves disclosed by Tamari, as suggested in the Office Action, will not result in the claimed device, which delivers *irrigation fluid to the treatment site* when excess pressure is exerted on the balloon. Accordingly, Stevens and Tamari, taken alone or combined, do not teach or even suggest the present invention.

Applicants further note that a person having ordinary skill in the art would not combine Tamari, which is directed to an extracorporeal pumping system for circulating blood, with Stevens, which is directed to an in vivo catheter anchoring balloon. These devices are entirely distinct devices that are used for different purposes. A person having ordinary skill in the art would not be motivated to combine a reference direct to an extracorporeal pumping system with an ablation system.

Claims 1-8 are therefore not obvious over Stevens and/or Tamari, and therefore represent allowable subject.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-24 are in condition for allowance.

In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with Examiner Chang is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

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Respectfully submitted,



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